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Treatment Modalities For Pharyngocutaneous Fistula Following Total Laryngectomy: A case series

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ABSTRACT

Pharyngocutaneous Fistula (PCF) is a life-threatening complication following total laryngectomy. This complication prolongs hospitalization and increases costs, and may lead to delays in postoperative radiotherapy. However, there is limited evidence regarding different management strategies, especially surgical treatments, for these patients. Sternocleidomastoid (SCM), Pectoralis Major (PM), submental island, supraclavicular, infrahyoid flaps, and Radial Forearm Free Flap (RFFF) are the most practical pedicled and free flaps for PCF surgical treatment.

In this study, we evaluated 24 patients with PCF out of 315 total laryngectomy patients. The management, including conservative and surgical treatments, was discussed, and risk factors for PCF occurrence were reported.

The patients' ages ranged from 42 to 79 years old, with an average of 62.8 years old.

15 cases (62.5%) had a history of radiotherapy, 2 were diabetic (8%), and the average hemoglobin was 12.82 gr/dl with an average blood albumin of 3.18 gr/dl. 3 cases (12.5%) had positive surgical margins, and neck dissection was done for 22 (%91.6).

6 patients (25%) responded to conservative management, with surgery performed for those who did not respond. Closure of the fistula using SCM muscle flap was done for 7 cases (29.16%), 3 (12.5%) were treated using PM flap, and other pedicled flaps were used in one case each. Successful management was achieved using RFFF for 2 patients (8.33%)

Treatment modalities first include conservative management, with surgical treatments using pedicled or free flaps as mandatory in cases of first-line failure. The selective flap is determined based on fistula characteristics and patient history.

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Introduction

After total laryngectomy, the occurrence of pharyngocutaneous fistula (PCF) is quite common, with a reported frequency ranging from 3% to 65% (1). According to the latest meta-analysis in international literature, the reported frequency of PCF is 14.3% for Primary Total Laryngectomy (PTL) and 27.6% for Salvage Total Laryngectomy (STL) (2). The occurrence of this event significantly prolongs hospitalization and increases costs, with patients experiencing PCF having an average hospital stay of 26-49 days compared to 17-9 days for those without PCF. Furthermore, this may lead to delays in commencing postoperative radiotherapy (RT) and can significantly impact the patient's psychological status (3-5). PCF is typically diagnosed between 6 and 11 days following surgery. Even though there is no definitive standard test for early diagnosis, indicators such as fever within the first 48 hours after surgery, persistent high output from the neck drain, wound redness and swelling, localized tenderness in the neck near the wound, and the presence of saliva at the wound after swallowing are all strong predictors of PCF development (6).

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Figure 1. Blue dye test for evaluation of pharyngocutaneous fistula

Multiple risk factors have been reported to comprehend the cause of this significant complication: past radiotherapy (RT) or chemoradiotherapy (CRT), the type of surgery, T (Tumor) and N (Nodal) stage, a brief interval between the conclusion of RT and laryngectomy, preoperative and postoperative hemoglobin levels below 12.5 g/L, comorbidities such as diabetes, liver diseases, or hypothyroidism, and surgical factors such as neck dissection and prior tracheotomy. In situations of delayed fistulization, the possibility of a second primary tumor of the piriform sinus should be taken into account (5).

The study by Weinberger et al. classifies PCF into 5 grades, and the treatment varies for each grade. They outlined the management for the 5 grades of PCF, with Grade 1 being essentially a controlled fistula (<5 cm in diameter) managed through the lateral neck drain without further breakdown and without changes in the clinical state. The fistula is safe, with no leakage and maintains stomal integrity. It is considered a safe fistula and will heal quickly with conservative measures. A minor central dehiscence with stomal leakage is classified as Grade 2, with maintained superior stomal integrity and no exposure of the great vessels. This safe fistula is most likely to heal with conservative measures. Grade 3 PCF demonstrates central wound dehiscence along with total superior stomal dehiscence from the superior skin flap. While the major blood vessels are not visible, there is a significant amount of salivary secretions present. Despite being a secure fistula where conservative methods could be effective, undergoing revision surgery with a flap can expedite complete recovery. Grade 4 PCF is characterized by a major central wound dehiscence with retraction of the superior skin flap, resulting in the exposure of a widely open neopharynx and subsequent contraction of the pharyngeal mucosal diameter. Despite being a safe fistula in terms of vascular rupture, reconstruction of the skin flap and pharyngeal remnants is essential. Grade 5 is characterized as a PCF with extension of both central and lateral exposing the great vessels and posing a high risk of rupture. This represents the typical dangerous fistula that necessitates immediate placement of a flap to cover the vessels and then close the fistula. In cases of life-threatening hemorrhage, further intervention such as angiography or ligation of the carotid artery may be necessary.

Although these types of classification for PCF would help the surgeon manage the patient, a gold standard treatment for PCF cannot be considered exactly. Also, most of the studies in the field of PCF following total laryngectomy have discussed the risk factors of its occurrence, while the way to manage the patient with fistula, especially the surgical treatment, is so crucial, which is missed in articles.

In this case series, the management of PCF following total laryngectomy, especially surgical management, has been discussed, and risk factors of these patients were also reported.

Case Presentation

All the patients diagnosed with laryngeal cancer based on direct laryngoscopy and biopsy during 2009 to 2015 were determined by hospital archive and an electronic-based logbook of surgeons. In the next step, the patients who underwent total laryngectomy surgery were extracted. Then patients with PCF were identified by referring to the total laryngectomy patient's documents. By using their files, the method of treatment and other factors of these patients were determined.

A total number of 1468 patients with laryngeal cancer, confirmed by direct laryngoscopic biopsy and pathological evaluation, were evaluated.

The study was done as a research project under the supervision of Tehran University of Medical Sciences, and there is no disclosure of potential conflicts of interest. The required information was extracted from the existing files.

Some of these patients have been treated with radiotherapy, Trans Oral Laser Microsurgery (TLM), or partial laryngectomy, and 315 of all 1468 cases have undergone total laryngectomy.

Among the 315 patients who underwent total laryngectomy, 24 cases had a pharyngocutaneous fistula.(%7.61)

All patients with PCF had SCC cancer. (One patient had chondrosarcoma, which is not included in these 24 patients.)

The age of patients with PCF ranged from 42 to 79 years old, with an average of 62.8 years old.

In terms of gender distribution of PCF, 21 patients were men and 3 were women.

Among the 24 patients with PCF, 15 cases (62.5%) had a history of radiotherapy, and 9 cases (32.5%) had no history of radiotherapy.

2 (%8) patients with PCF were diabetic, and 22 (92%) patients were non-diabetic.

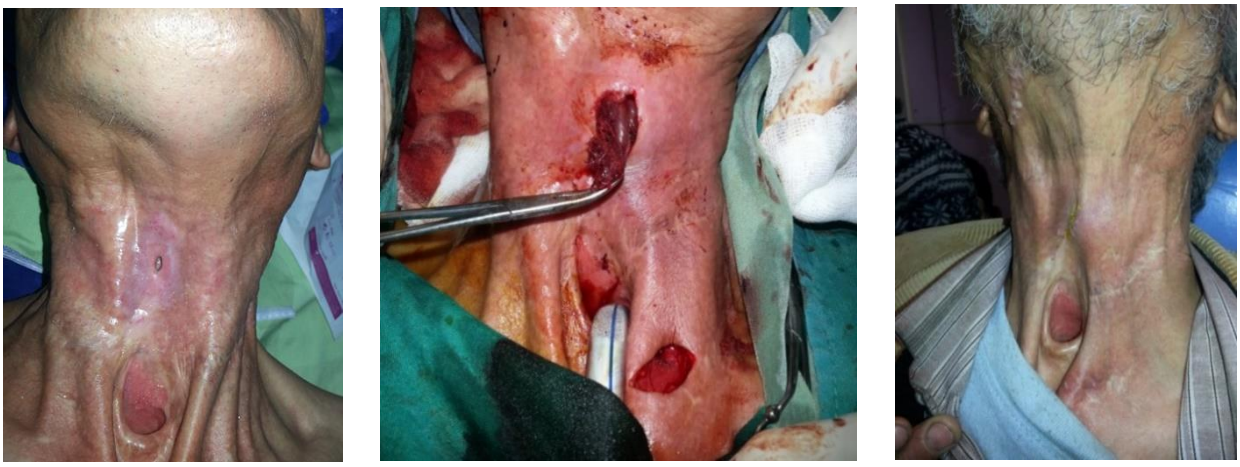
The average hemoglobin of patients with PCF was 12.82 gr/dl, and the average blood albumin was 3.18 gr/dl.

Among patients with PCF, 21 cases (87.5%) had negative surgical margins, and 3 cases (12.5%) had positive

surgical margins.
22 cases (91.6%) of Patients with PCF underwent neck dissection, and neck dissection was not done for 2 cases.(%8.4)
The time of PCF occurrence was from the sixth to the fifteenth days after the operation.
In order to control this complication, different managements were done. At first, conservative treatment started for all patients with PCF. Conservative treatment included feeding the patient through gavage (the patient was NPO), taking care of the wound and dressing, prescription of antibiotics (usually ceftriaxone and clindamycin), swallowing 1% acetic acid every 8 hours, and packing of surgicel soaked in acetic acid in the fistula tract (Figure 2).

Figure 2. Insertion of surgicel in fistula tract (conservative management)

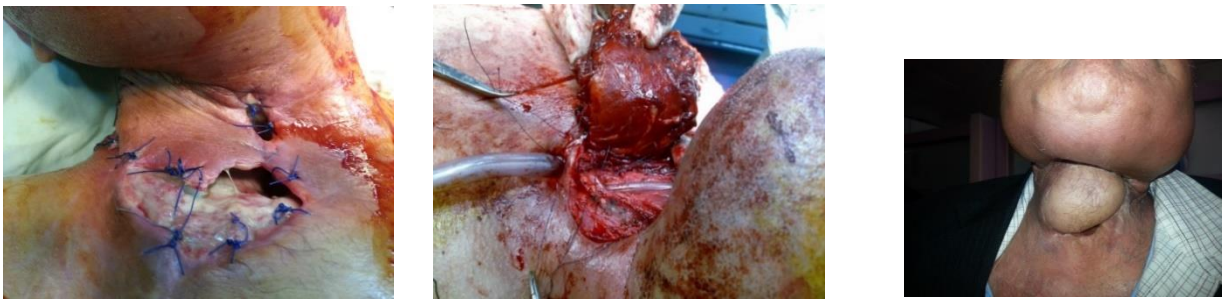
Among 24 patients with PCF, 6 cases (25%) responded to conservative treatment during 15 days, which means the volume of saliva in the wound reduced.
Surgery was done for patients who did not respond to conservative management. The type of flap was chosen according to the availability of desired tissue. Closure of the fistula using sternocleidomastoid (SCM) muscle flap was done for 7 cases (29.16%). Figure 3 shows SCM muscle flap in closure of PCF and post operation healing of PCF .



A *B* *C*

Figure 3. Surgical management of pharyngocutaneous fistula (SCM muscle flap) (A). Pre operative view of pharyngocutaneous fistula (B). Technique of surgery using step ladder incision (c). Post operative view after 3 months

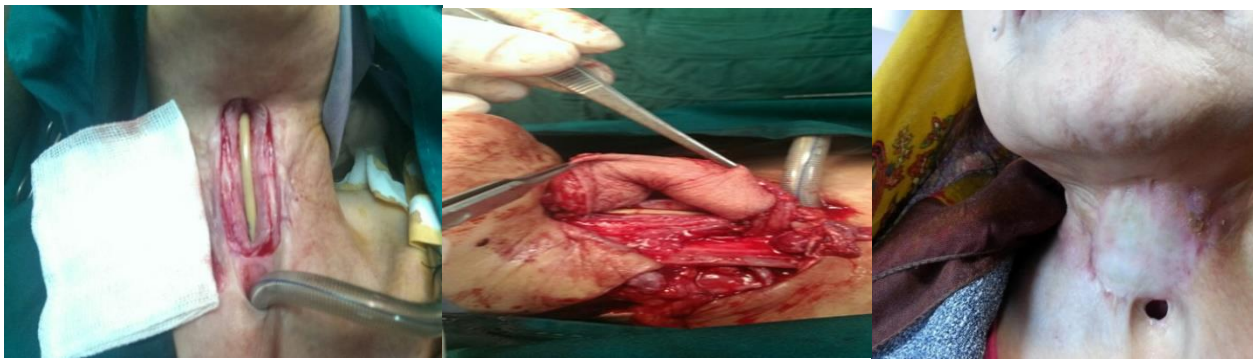
Pectoralis Major (PM) muscle flap was used in 3 cases (12.5%). Figure 4 shows the procedure and result of using this flap.



A B C

Figure 4 . Surgical management of pharyngocutaneous fistula (major pectoralis muscle flap) (A). Pre operative view of pharyngocutaneous fistula (B). Technique of surgery (c). Post operative view after 2 months

2 patients with PCF were treated with radial fore arm free flap (8.33%) as shown in figure 5.



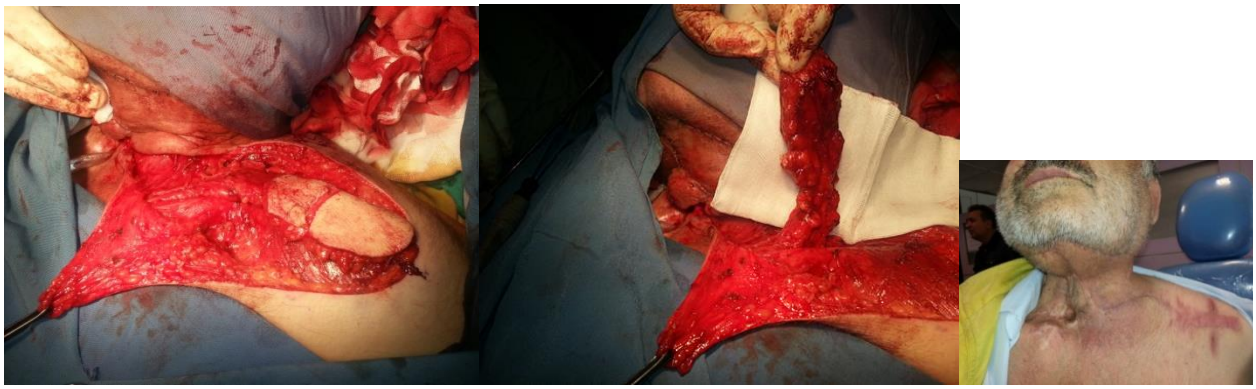
A B C

Figure 5. Surgical management of pharyngocutaneous fistula (radial for arm free flap) (A). Pre operative view of pharyngocutaneous fistula (B). Technique of surgery (C). Post operative view after 4 months

Each of the deltopectoral flap, submental flap, supraclavicular flap and infrahyoid flap was used in one case (4.16%). Figures 6 and 7 show submental and supraclavicular flaps for surgical management of PCF respectively.

A B C

Figure 6. Surgical management of pharyngocutaneous fistula (submental flap)) (A). Pre operative view of pharyngocutaneous fistula (B). Technique of surgery (C). Post operative view after 3 months



A B C

Figure 7. Surgical management of pharyngocutaneous fistula (supraclavicular flap) (A and B). Technique of surgery (B). Post operative view after 3 months

Three patients with PCF who had positive surgical margins were treated with radial forearm flap and gastric pull-up surgery. All patients were followed up for 6 month. Table 1 summarizes the characteristics and different managements of the patients with PCF.

Table 1. Characteristics and management of patients with pharyngocutaneous fistula

Management modality	Surgical margin	Neck dissection	Albumin	Hemoglobin	Diabetes mellitus	History of radiotherapy	Smoker	Gender	Age
conservative	no	yes	3/2	13/4	no	no	yes	male	59
conservative	no	yes	3/4	12/8	no	yes	yes	male	70
conservative	no	yes		13/7	yes	no	yes	male	42
Radial fore arm free flap	yes	yes	3/2	12/9	no	yes	yes	male	65
Major pectoralis flap	no	yes	2/6	12/2	no	yes	yes	male	54
Gasteric pull up	yes	yes	3/1	11/8	no	yes	yes	male	76
Radial fore arm free flap	no	yes	2/8	12/4	no	yes	yes	female	57
SCM flap	no	yes	2/9	11/8	no	yes	yes	male	54
SCM flap	no	yes	3/6	12/6	no	yes	yes	male	52
Gasteric pull up	yes	yes	2/7	12/2	no	no	yes	male	76
Submental flap	no	yes	3/2	12/7	yes	no	yes	male	76
Deltopectoral flap	no	no	3/6	13/4	no	yes	yes	male	77
Major pectoralis flap	no	yes	2/8	11/8	no	yes	yes	male	56
conservative	no	yes	3/5	13/4	no	yes	yes	male	67
Major pectoralis flap	no	yes	2/9	12/8	yes	no	yes	male	72
Infra hyoid flap	no	yes	3/4	13/2	no	yes	yes	female	72
SCM flap	no	yes	3/4	13/2	no	no	yes	male	66
SCM flap	no	yes	2/8	12/1	no	yes	yes	female	79
conservative	no	yes	3/4	13/5	no	no	yes	male	62
Supraclavicular flap	no	yes	3/4	13/2	no	yes	yes	male	60
SCM flap	no	yes	3/4	12/8	no	no	yes	male	65
SCM flap	no	no	3/6	13/4	no	no	yes	male	49
conservative	no	yes	3/2	13/2	no	yes	yes	male	62
SCM flap	no	yes	3/4	13/4	no	yes	yes	male	60

Discussion

The majority of postoperative pharyngocutaneous fistulas (PCF) following total laryngectomy can be successfully closed with conservative management. However, in cases where the neck has been previously irradiated, spontaneous closure is less likely to occur, as demonstrated in our study (none of the patients who underwent salvage total laryngectomy were cured with conservative management). The appropriate management of PCF depends on factors such as the size of the fistula, the amount of remaining pharyngeal mucosa, and the condition of the surrounding neck skin. Various reconstructive techniques have been described to effectively close PCF. The key surgical principle is to ensure that the epithelial surfaces are brought together without tension and to utilize well-vascularized tissue for secure neck closure. Different regional flaps,

including the sternocleidomastoid, PM, submental, and supraclavicular flaps, have been described for PCF closure (6- 11).

The SCM muscle is rarely utilized in the literature; its harvesting is limited in cases of prior radical neck dissection and becomes challenging when patients have received pre or postoperative RT. Kilic et al (12) detailed the application of a myocutaneous SCM flap in 3 patients, yielding positive outcomes. On the other hand, Raman et al (13) outlined a surgical technique involving the sternocleidomastoid muscle without the cutaneous covering for closing a PCF in a patient who had undergone PTL . In our study we applied SCM flap without cutaneous cover in 29.16% of patients with PCF with successful result. 6 and 4 of these patients underwent neck dissection and had history of radiotherapy respectively, Although most of previous studies described limitations for SCM flap in salvage laryngectomy or in patients who underwent neck dissection. This fact seems to be related to surgical technique and needs to be evaluated in studies with larger samples.

The use of the PM flap with an overlying skin island for partial pharyngeal reconstruction was first described by Theogaraj et al in 1980. This method offers several advantages, including ease of harvest, reliability and proximity to the neck. It provides bulk, which eliminates dead space and protects the carotid vessels. The PM flap can be harvested as a muscle flap to reinforce pharyngeal closure or raised as a musculocutaneous flap using the skin for either pharyngeal or cervical skin closure. The insertion of the PM flap skin island into the pharyngeal repair increases the diameter of the reconstructed pharynx and has the potential to reduce the incidence of pharyngeal stenosis. Despite partial pharyngeal reconstruction with this method, stenosis occurred in 2 of 15 cases (13.3%) (11).In our series 12.5% of patients with PCF managed with PM flap. Stenosis or re- fistualization was not occurred and all 3 patients were cured in a 6 months follow up.

The submental artery island flap is a versatile and durable reconstructive flap utilized for closing facial defects. It can be easily elevated on one side and rotated to cover the entire homolateral face and neck. In specific situations, this flap can also be employed for closing pharyngocutaneous fistulas, even in heavily irradiated tissue. One of the main limitations of this method is the necessity of a previous bilateral neck dissection where both facial arteries may have been ligated. Nevertheless, in patients with a history of ipsilateral neck dissections, the submental artery island flap can be successfully raised on the contralateral side pedicle and inserted into the defect. Demir et al. documented the closure of pharyngocutaneous fistulas in 9 patients who had undergone primary total laryngectomy and adjuvant radiotherapy; no intra- or post-operative complications were noted, and the closure rate was 100% at the last follow-up (14). One patient with PCF was treated using submental flap in our study and he had the history of bilateral elective neck dissection for 2 to 4 levels. (facial artery is usually closed in level one neck dissection)

Pabiszczak and colleagues reported the results of utilizing a regional pedicled fasciocutaneous supraclavicular flap in 6 patients who had salvage total laryngectomy following chemoradiotherapy; the failure rate was 17% (1/6 flaps). Due to its thinness, flexibility, good blood supply, and proximity to the primary surgical site, the fasciocutaneous supraclavicular flap could serve as a viable option compared to other free and pedicled flaps. It is known for having a low rate of donor site complications, being easy and quick to harvest, it is particularly recommended for patients with underlying medical conditions. The contraindications are limited overall, making it a potential solution for challenges posed by prior bilateral neck dissection and radiation therapy at the surgical site (15).Our series included one treatment with this flap in a PCF after salvage total laryngectomy.

In cases where local tissues are not accessible for fistula closure, the reconstruction of pharyngeal and cervical tissue becomes even more challenging. This process involves mobilizing distant tissues for internal lining and external coverage. The use of free tissues offers several benefits, including the distance from previously irradiated or infected tissues, well-vascularized flaps that can repair complex PCFs. However, a major limitation is the availability of suitable neck vessels for microvascular anastomosis, along with the fragility and comorbidities of patients that may make these procedures unsuitable. Despite these challenges, free flaps are increasingly being used to prevent and treat PCFs, offering advantages such as reliability, easy elevation, minimal donor morbidity, and the ability for a two-team approach (16).

The Bohannon et al study presented the largest case series, with 22 free flaps performed in 20 patients. The majority of patients (86%) underwent radial forearm flap (RFFF) reconstruction, while other flaps such as anterolateral thigh (ALT) and rectus free flaps were also used. It is worth noting that the initial free flap procedure had a fistula closure rate of 50%. Half of the patients experienced a leak on barium swallow or refistulized, requiring additional procedures. However, after a second free flap, simultaneous pectoralis pedicled flap, or additional local flaps, an overall closure rate of 85% was achieved. These findings suggest that there may be challenges in closing PCFs with a free skin flap in the first repair surgery alone, leading the authors to recommend the use of both RFFF and pedicled pectoralis muscle to reconstruct both the pharyngeal lining and external skin.

2 patients including one female and a man with history of neck dissection and radiotherapy were managed with RFFF and there was no need for pedicled flap unlike Bohannon et al study, so further studies are necessary to evaluate this issue.

Other treatment options including Negative-Pressure

Wound Therapy (NPWT) or Hyperbaric Oxygen Therapy (HBOT) are described in articles such as Steinbichler et al (17) and Molteni et al (18)studies, which our series did not include these modalities. So our study could be developed to larger samples and more treatment modalities, with the aim of comparing the complications and advantages of each surgical method to help the surgeon choose the best surgical treatment.

Availability of data and materials

Data are available from the corresponding author upon reasonable request

Competing interests

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The management of PCF after laryngectomy includes a wide variety of treatment modalities. To choose the best therapy for PCF healing, not only the features of the fistula are important but also the general conditions of the patient and the previous administered treatments should be considered. A first attempt of conservative management is mandatory in all cases of PCF. In case of failure of conservative management, surgical treatment should be considered, with different flaps available for closure. Each of these flaps has advantages and disadvantages, and the surgeon can choose based on the patient's condition.

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